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February 15, 2000

Dockets Management Brance (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA:

We are submitting written comments on your proposed rule, **Requirements for Testing Human Blood Donors for Evidence of Infection Due to Communicable Disease Agents**, which was published August 19, 1999 in the *Federal Register (Volume 64, Number 160, Pages 45339-45355*). Our comments are specifically directed towards the proposed requirement to test each autologous donation for evidence of infection due to HIV, types 1 and 2, HBV, HCV and HTLV, types I and II.

We are against the proposed requirement to test each autologous donation for the routine battery of infectious disease markers.

The proposed infectious disease testing will not improve the safety of the *allogeneic* blood supply. Since there is no scientific evidence that such testing of *autologous* units, or having knowledge of infectious disease testing results, would provide an increased margin of safety to the general blood supply. Additionally, there is no evidence that infectious disease testing would provide an additional level of safety to individuals who handle autologous units.

The clerical errors may result in an autologous unit being transfused to the wrong patient. Or, just as likely, that the patient who has donated autologous units will erroneously be transfused with allogeneic units. Procedural and system controls, labeling changes, storage and isolation requirements, etc. are more likely to prevent such clerical errors. There is no evidence that simply having knowledge of potential infectivity increases, or necessarily changes, how a particular unit of blood will be handled or issued. **The practice of Universal Precautions assures that each unit is handled in a similar fashion.**

The mandatory testing of each autologous donation would add cost without proven benefit, indeed millions of dollars may be saved by not performing infectious disease testing. Until real data is obtained on how many millions of dollars are currently being spent to test autologous units, and what percentage is being tested, the FDA's monetary impact estimation must be suspect. Given the fact that nationwide only 50% of predeposit autologous blood is transfused, this testing would be an added unnecessary wastage to an already stressed healthcare.

The collection and transfusion of infectious disease marker-positive autologous units would still be available to the patient, and for shipping, with a physician's written approval. This will not increase the safety of the blood supply.

The FDA's proposal to require infectious disease testing of autologous donations does not address the blood collected by intraoperative hemodilution, intraoperative salvage techniques or post-op salvage devices. The inadvertent transfusion of intraoperatively collected blood to the wrong patient is just as real and significant as that involving preoperatively collected units.

In view of what we currently know about autologous blood collection and transfusion, efforts would be better directed towards optimizing labeling requirements, such as greater use of biohazard labels and perhaps changing the unit identification label. Regulations related to the segregation of autologous units in storage areas, which most facilities currently do, should also be addressed before rushing to mandate a policy of universal infectious disease testing.

I appreciate the opportunity to comment on this proposed rule. Thank you.

Sincerely,

Bala B. Carver, MD
Medical Director, Transfusion Medicine

Kathleen Mundt, MS MT(ASCP)SBB
Technical Specialist, Blood Bank

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